

REMARKS/ARGUMENTS

Claims 1-25 are pending in this application. Claims 1, 2, 4, 6, 8, 10, 13, 15, 17, 18, 21, 23 and 24 have been amended. Review and reconsideration on the merits are requested in view of the foregoing amendments and the following discussion.

Claims 2, 4, 6, 8, 12, 13, 15, 17, 18, 21, 22 and 24 stand rejected under 35 U.S.C. § 112, second paragraph, as being indefinite. The Examiner has objected to the term “from about” in the claims as being indefinite. Applicants have amended these claims to delete the term “from” from the claims. As argued in the previous response, applicants submit that the term “about” is a widely accepted term to avoid strict numerical limitations. Therefore, applicants respectfully submit that the rejected claims as amended are in compliance with 35 U.S.C. § 112 and request that the rejection be withdrawn.

Claims 1-11 stand rejected under 35 U.S.C. § 112, first paragraph, as being non-enabled for preventing conditions associated with calcium and/or magnesium deficiency. Applicants request a clarification of this rejection. According to the Office action, the specification is “enabling for decreasing serum level of triglycerides in mammals” but fails to “provide enablement for preventing condition associated with calcium and/or magnesium deficiency.” Office Action, page 4. Reference to decreasing levels of triglycerides was also in the previous Office action and is repeated in this Office action although the current application makes no reference to decreasing serum levels of triglycerides. Furthermore, in the previous response, applicants deleted the reference in claim 1 to preventing conditions associated with calcium and/or magnesium deficiency. Therefore, applicants respectfully request clarification and question the appropriateness of this rejection. Nonetheless, applicants have amended claim 1 to simply refer to treating calcium and/or magnesium deficiency in a subject having a deficiency in calcium and/or magnesium serum levels. Therefore, applicants submit that the claims as amended satisfy the enablement requirement and request that the rejection be withdrawn.

Claims 1, 3, 5-6, 9, 11, 12 and 14 stand rejected as being anticipated by U.S. Patent No. 6,031,000 to Nissen et al. It is respectfully submitted that the Nissen document fails to disclose or suggest the present invention. Independent claim 1 as amended recites treating a subject

having a deficiency in calcium and/or magnesium serum levels. Likewise, claim 12 refers to providing a nutritionally supplemental amount of calcium and/or magnesium to a subject in need of a nutritionally supplemental amount of calcium and/or magnesium. These limitations are not disclosed or described in Nissen. The claim language requires that the composition be administered to a subject having a deficiency in calcium and/or magnesium serum levels or to a subject in need of a nutritionally supplemental amount of calcium and/or magnesium, respectively. Nissen fails to disclose either of these limitations and, therefore, there can be no anticipation. Furthermore, to the extent that the Office has taken the position that such disclosure is inherent, applicants respectfully disagree. Reliance on inherency requires a showing that the “allegedly inherent characteristic necessarily disclose from the teachings of the applied prior art.” *Ex parte Levy*, 17 U.S.P.Q. 2d 1461, 1464 (Bd. Pat. App. & Inter. 1990) (Emphasis in original). Applicants are claiming a new use for a composition and the prior art fails to disclose or describe this new use. In construing similar claim language, the Board of Patent Appeals and Interferences interpreted a claim for treatment of sleep apnea by administering a compound to a patient in need of such treatment to require that the method be practiced with the intent to treat the sleep apnea. *Rapoport v. Dement*, 254 F.3d 1053, 1059 (Fed. Cir. 2001). Prior art disclosing treatment of anxiety and breathing difficulty, a symptom of apnea, was insufficient to anticipate or render obvious the claim. Therefore, applicants respectfully request that the rejection be withdrawn.

Claims 1, 5-6 and 9 stand rejected as being anticipated by the Vukovich article. According to the Office action, claim 1 is broadly interpreted to include any condition associated with calcium and/or magnesium. Claim 1, as indicated above, has been amended to recite treating a subject having a deficiency in calcium and/or magnesium. Vukovich never indicates or suggests that the composition is being administered to address calcium and/or magnesium deficiency. Therefore, applicants respectfully submit that the claims are novel over Vukovich and request that the rejection be withdrawn.

Claims 1, 5-6, 7-9 and 12 stand rejected over WO 94/17678. Again, the Examiner has pointed to a disclosure in the reference that could be loosely related to bone loss and, therefore, a condition associated with calcium and/or magnesium in the reference. The reference does not

disclose or suggest treating calcium and/or magnesium deficiency by administering a mineral supplement containing calcium (HMB), magnesium HMB or both to a subject having a deficiency in calcium and/or magnesium serum levels. Therefore, applicants respectfully request that the rejection be withdrawn.

Claims 1-25 stand rejected as being unpatentable over Nissen et al. taken with Vukovich et al. and the '678 publication further in view of www.naturalconnections.com (1998). The Office action indicates that it would have been obvious to combine these references to arrive at the present invention. However, applicants respectfully submit that the Office has failed to establish a *prima facie* case of obviousness because one of ordinary skill in the art considering these references would not be led to the present invention. Applicants respectfully submit that there is insufficient motivation for combining the disclosures in the cited documents to arrive at the present invention. Nissen is only concerned with salt capable of carrying the HMB and provides no disclosure or suggestion with respect to using the salts as a calcium and/or magnesium supplement or to increase blood serum levels of magnesium and/or calcium in a patient having low levels of these elements. Likewise, the Natural Connections' website describes a combination of magnesium and calcium and discloses various salts that can be used. Nonetheless, it fails to disclose a mineral supplement containing calcium HMB and/or magnesium HMB. There is no indication or suggestion as to why one of ordinary skill in the art would be motivated to use something other than the commonly available supplements. Furthermore, as described in the specification, CaHMB exhibits a significant increase in elemental calcium compared to other calcium salts used in typical supplements. The same holds true for MgHMB when compared to commercial magnesium supplements, such as magnesium lactate. The present invention satisfies a long felt but unmet need in the art for a supplement containing calcium and/or magnesium salts of increased bioavailability. Therefore, applicants respectfully request that these rejections be withdrawn.

Furthermore, with respect to claims 2, 17, 18 and 19-25, which are directed to methods and compositions containing a combination of calcium and magnesium, the cited references fail to render such compositions obvious. In fact, the Nissen references specifically teach away from such a composition containing both calcium and magnesium. Nissen and the other references

focus on calcium salts only, never disclosing or suggesting a composition containing both calcium and magnesium. Therefore, one of ordinary skill in the art reviewing the cited documents would never be motivated to make such a joint composition because there is no motivation in the art to do so. The present invention provides magnesium and calcium salts having improved solubility and bioavailability compared to commercially available supplements. Therefore, for at least this reason as well, applicants submit that these claims are patentable under the cited references and request that the rejections be withdrawn.

The claims also stand rejected based on double patenting over U.S. Application No. 10/667283. Applicants will attend to the provisional double patenting rejection when one of these two applications issues as a patent.

In view of the foregoing, it is respectfully submitted that claims currently pending are distinguishable from the references cited and are in condition for allowance. Reconsideration of the rejections of record is respectfully requested. The Commissioner is authorized to charge any additional fees required or to credit any overpayment to Deposit Account No. 20-0809. If the examiner wishes to discuss any aspect of this response, please contact the undersigned at the telephone number indicated below.

Respectfully submitted,

/John F. Kane/
John F. Kane, Reg. No. 44,815

THOMPSON HINE LLP
2000 Courthouse Plaza, N.E.
10 West Second Street
Dayton, Ohio 45402-1758
937-443-6816